Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of the transdiagnostic therapy based on emotion regulation with religious/spiritual design versus Barlow transdiagnostic therapy on symptoms and general function in women with anxiety disorders

Protocol summary

Study aim
the purpose of this study is Comparing the effect of the transdiagnostic Therapy Based on emotion regulation with Religious / Spiritual Design versus the Barlow's transdiagnostic Therapy on Symptoms and general function in Women with Anxiety Disorders.

Design
in this research, 10 eligible women with one of the anxiety disorders referring to Mehre Shefa health center in Yazd were chosen and were randomly divided into two groups of treatment.

Settings and conduct
This research is performed in the Mehre Shefa health Center in Yazd. The participants in the research are unaware about type of treatment they recieved.

Participants/Inclusion and exclusion criteria
Entrance conditions: Female gender; Age of 18-30 years; Minimum high school diploma education; principal diagnosis of anxiety disorder based on DSM-5; Full satisfaction for attending sessions. Non-entrance Conditions: having Schizophrenia and other psychotic disorders; having Obsessive-compulsive disorder and related disorders; having Post traumatic stress disorder and related disorders; having Bipolar disorder and related disorders; having Substance and Alcohol abuse ; having substance/medication-induced anxiety disorder ; history of suicidal thoughts and attemps; taking medication or receiving psychotherapy during the last 6 months for the treatment of anxiety disorders.

Intervention groups
The two intervention groups consist of the transdiagnostic therapy based on emotion regulation with religious/spiritual design and Barlow's transdiagnostic therapy. Each treatment includes 12 one-hour sessions , which performed individually. in this study, no control group was used.

Main outcome variables
general symptoms of anxiety; General symptoms of depression; General function

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180104038214N1**
Registration date: **2018-08-08, 1397/05/17**
Registration timing: **retrospective**

Last update: **2018-08-08, 1397/05/17**
Update count: **0**

Registration date
2018-08-08, 1397/05/17

Registrant information

Name
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Tarbiat modares university
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-09, 1396/10/19
Expected recruitment end date

2018-02-08, 1396/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of the transdiagnostic therapy based on emotion regulation with religious/spiritual design versus Barlow transdiagnostic therapy on symptoms and general function in women with anxiety disorders

Public title

Comparing the effect of two transdiagnostic therapy on symptoms of anxiety disorders

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Female sex Age 18-30 years Have at least high school diploma Having one of the anxiety disorders based on DSM-5 Having full satisfaction to participate in sessions

Exclusion criteria:

Having schizophrenia and other psychotic disorders Having Obsessive-compulsive disorder and related disorders Having Post traumatic stress disorder and related disorders Having Bipolar mood disorder and related disorders Having substance and alcohol abuse Having substance/medication-induced anxiety disorder Having a history of suicidal thoughts and actions taking medication or receiving psychotherapy during the past 6 months for the treatment of anxiety disorders lack of religious adherence

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple randomization through lottery Random unit: Individual

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics comittee of Iran University of Medical Sciences

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NO. 1., Mansoori ave., Niayesh street, Sattarkhan Blvd.

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Approval date

2018-02-28, 1396/12/09

Ethics committee reference number

IR.IUMS.REC 1396.32515

Health conditions studied

1

Description of health condition studied

Phobic disorders

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

2

Description of health condition studied

generalized anxiety disorder

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

3

Description of health condition studied

panic disorder

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

Primary outcomes

1

Description

anxiety symptoms

Timepoint

before intervention, Sessions 3, 6, 9,12 of therapy and

one-month and three-month follow-up

Method of measurement

Beck anxiety disorder, adult version of Screen for Child Anxiety Related Emotional Disorders (SCARED-A), generalized anxiety disorder scale- 7(GAD-7)

2

Description

general function

Timepoint

before intervention, Sessions 6, 12 of therapy and one-month and three-month follow-up

Method of measurement

Work and Social Adjustment Scale (WSAS)

Secondary outcomes

1

Description

depression status

Timepoint

2 stages in baseline, sessions 3, 6, 9, 12 and one-months and three-months follow-up

Method of measurement

beck depression inventory (BDI)

Intervention groups

1

Description

first Intervention group: transdiagnostic therapy based on emotion regulation with religious / spiritual design. The treatment protocol includes 12 one-hour session which run weekly and for three months. The titles of the sessions are, respectively, 1.the preparation for the treatment and enhance motivation of client, 2. understanding emotions in the balanced system of human, 3. introducing the role of cognition in regulating and modifying emotions to client, 4. identifying and modifying the god-images of client, 5. adapting the cognitive evaluations of client with god concept, 6. identifying the world- images of client and modifying them, 7. identifying the hereafter- images of client and modifying them, 8. behavioral self-caring, 9. awareness of physical feelings and reinforcement tolerance of them, 10.directing awareness to god, 11. Intrinsic and situation-based emotional exposure 12. relapse prevention

Category

N/A

2

Description

second Intervention group: Barlow transdiagnostic therapy. This intervention includes 8 modules, each module taking between one or two sessions. Modules include: 1. Increasing the motivation for participate in treatment, 2. Psychological training and seeking emotional experience, 3. Mindfulness-based emotional awareness, 4. Cognitive flexibility, 5. emotional avoidance and emotional behaviors, 6. awareness and tolerance of physical feelings, 7. Intrinsic and situation-based emotional exposure, 8. Prevention of relapse. sessions lengthen from 8 to 12 sessions and between approximately 50 to 60 minutes. sessions are held on a weekly basis.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehre Shefa Health Center

Full name of responsible person

Hossein Mahdian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is publishable after unrecognizing people. Designed protocol of transdiagnostic therapy based on emotion regulation with religious / spiritual design is Shareable. The data analysis plan includes visual charts in single case studies, and statistical indicators of Improvement percentages and effect sizes.
When the data will become available and for how long
6 months after the publication of results
To whom data/document is available
academic reasherchers

Under which criteria data/document could be used

treatment protocol can be used to evaluate its efficacy in other clinical groups and to compare its efficacy with other therapeutic protocols.

From where data/document is obtainable

roghaye sadat mirjalili mirjalili.r14@gmail.com

What processes are involved for a request to access data/document

The applicant must send an email in order to receive files and the documents and a request files will be sent for a maximum of two weeks.

Comments